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ZARLEY MCKEE THOMTE VOORHEES & SEASE PLC
SUITE 3200
801 GRAND AVENUE
DES MOINES, IA 50309-2721

EXAMINER

EINSMANN, JULIET CAROLINE

ART UNIT PAPER NUMBER

1655

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17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/380,419

Applicant(s)

ROTHSCHILD ET AL.

Examiner

Juliet C Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 20-23 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 20-23, and 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

1. This action is written in response applicant's correspondence submitted 9/26/01, paper number 16. Claims 1, 2, 4-6, 10, 12, 20, 23, 28, 29, 31, and 32 have been amended, claims 13-19 and 24-27 have been canceled, and claim 33 has been added. Claims 1-12, 20-23, and 28-33 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

Priority

2. Priority is granted in this case to the instant filing date. Although the cited provisional applications contain disclosure of the polymorphism used in the instant methods, they do not provide adequate support for the instantly claimed screening methods.

Sequence Rules

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s):

(A) The sequence identifiers used on page 7 do not match up with the sequence listing.

(B) The sequences recited in Fig. 7 must be identified with proper sequence identifiers.

(C) The nucleic acid sequences recited in figure 5 must be identified with proper sequence identifiers.

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In order to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), Applicant must correct these problems. If applicant chooses to submit a new CRF and paper copy, Applicant must submit a new CRF and paper copy of the Sequence Listing containing these sequences, an amendment directing the entry of the Sequence Listing into the specification, an amendment directing the insertion of the SEQ ID NOs into the appropriate pages of the specification and a letter stating that the content of the paper and computer readable copies are the same.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-12, 20-23, and 28-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of identifying a pig which possesses a genotype indicative of the pig having less back fat than pigs with a different genotype, indicative of the pig having a lower daily gain than pigs with a different genotype, or of the pig having a lower feed intake than a pig with a different genotype, wherein said method comprises screening DNA of the pig for a G → A point mutation at position 678 of SEQ ID NO: 1 (of the sequence listing) and wherein the absence of the mutation is indicative of a pig having the recited traits, does not reasonably provide enablement for methods which screen other animals or methods which utilize other polymorphisms. The specification does not enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The prior art teaches one polymorphism in humans which is associated with obesity (Yeo *et al.* 1998. *Nature Genetics*, Vol. 20, p. 111-112). Methods for screening humans using this polymorphism are also enabled.

Each of the rejected claims are broadly drawn to include at least one of the following: methods for screening any animal or methods for using polymorphism any polymorphism in the seventh transmembrane domain of the MC4R gene.

The specification provides a single working example which demonstrates that in pigs homozygous for an G at position 678 of SEQ ID NO: 1 is correlated with pigs that have less backfat, lower daily gain, and lower feed intake than pigs homozygous for an A at position 678. The prior art is silent with respect to other possible polymorphisms in the MC4R gene or with respect to the association of this particular polymorphism with any metabolic trait in any other animal. Neither the specification nor the prior art provide evidence of any universal correlation between polymorphisms in MC4R and metabolic traits which would conclusively associate the polymorphism instantly disclosed with metabolic traits in any other animal.

The art is highly unpredictable with regard to the presence and functionality of polymorphic sites in genomic DNA. The amount of direction or guidance presented in the specification and the prior art of only one point mutation in the MC4R gene of one species of animal is minimal, given that just the redundancy of the genetic code would allow for several thousand different sequences when conserved or non-conserved mutations are considered, millions of different sequences for the pig MC4R gene may exist which may, or may not, have

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substantial functional differences or association with the traits of interest herein. There are no working examples of additional sequences other than those disclosed in either the specification or the prior art.

Furthermore, there is no evidence in the specification provided that the identified polymorphism is causative of the observed traits. This is a significant absence of evidence, since it is possible that the polymorphism is merely a marker for the causative genotype. In light of the fact that the causative genotype has not been identified, it is unpredictable as to whether or not markers which are linked to the instantly disclosed polymorphism would be informative for the traits of interest herein (for example, as claimed in claims 29 and 30).

Although the level of skill in the art of nucleic acid analysis is high (the Ph.D. degree with laboratory experience), the quantity of experimentation that would be necessary to determine even one additional polymorphism in the pig MC4R gene is substantial since there is no predictability for which sequences exist which code for polymorphisms in pig MC4R genes. Applicants have not disclosed how one would go about detecting additional polymorphisms associated with the traits of interest herein. Because there is no reason to expect that any additional polymorphism is associated with the instantly discussed metabolic traits and because of the very large number of possible polymorphisms, screening for additional polymorphisms that would be indicators of these traits would require the rearing and subsequent slaughtering of many, many pigs in order to analyze their metabolic traits and in order to screen the MC4R gene for informative polymorphisms. There is no evidence, however, of any frequency of significant polymorphisms. Further, even if polymorphisms were detected, the polymorphism may not correlate to polymorphic traits. The instantly disclosed polymorphism may be coincident with

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and unrelated to a different, unlinked (on the chromosome) polymorphism such as another MC4R polymorphism or a polymorphism in an undetermined gene that actually determines the metabolic traits. The instantly disclosed polymorphism would not have any meaning or effect, but might appear to influence metabolic traits due to its close proximity to some other gene.

Furthermore, the level of unpredictability and the level of experimentation required to expand the instantly disclosed methods to include animals of other species are also quite high. There is no teaching in the specification that the disclosed polymorphism even exists in animals of other species. Since there is not evidence that the disclosed polymorphism is causative of the traits (as discussed above), it is highly unpredictable as to whether the polymorphism would mark the same traits in other animals. Further, in order to provide such evidence the skilled artisan would be required to undertake extensive studies of the metabolic traits of hundreds upon hundreds of different individual animals of each of many different species of animal. Such experimentation would be inventive in itself.

Due to the broad nature of the claims, the presence of only one working example, the extreme unpredictability of polymorphisms in the art, combined with the absence of teaching in the prior and the large quantity of experimentation necessary in the art support a conclusion that undue experimentation is required to make and use the invention as broadly claimed.

6. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

In the instantly rejected claims, the new limitation of "allele specific oligonucleotide primers" in claim 10 appears to represent new matter. No specific basis for this limitation was identified in the specification, nor did a review of the specification by the examiner find any basis for the limitation. The specification provides methods for PCR amplification of portions of the bovine MC4R gene, but none of these methods appear to employ allele specific oligonucleotides. Since no basis has been identified, the claims are rejected as incorporating new matter.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-12, 20-23, and 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite over the recitation of "possesses a genotype having a genetic marker" because it is not clear how a genotype can have a genetic marker. A genotype is defined as the particular genetic pattern seen in the DNA of an individual. "Genotype" is usually used to refer to the particular pair of alleles that an individual possesses at a certain location in the genome. Thus, the genotype does not have the marker, but describes the allele present at the

location of the marker. It would be more appropriate to say that the animal possesses a particular genotype (i.e. a "G" at position 678 of SEQ ID NO: 1) or that the animal possesses nucleic acid comprising a specific version of a marker. Claims which depend from claim 1 are indefinite for this reason as well.

Regarding claim 1, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Thus, it is not clear if the method is for identifying an animal which possesses a genotype indicative of variation in fat content, growth rate, and feed consumption, or if the method is for detecting an animal which possesses a genotype indicative of variation in any metabolic trait of which those recited are a few examples. Claims which depend from claim 1 are indefinite for this reason as well.

Claim 1 is further indefinite because steps (a) and (b) appear to conflict. Step (a) requires obtaining a nucleic acid sample, while step (b) requires identifying a polymorphism in a protein. Claims which depend from claim 1 are indefinite for this reason as well.

Claim 1 is further indefinite because it is not clear what this method accomplishes. The method appears to be a method for identifying an animal which possesses a genotype for a marker associated with particular traits. It would seem that any animal screened for such a marker would in fact have a marker that is associated with the recited traits. The claim does not specify that a particular genotype is being identified, only that an animal which possesses a genotype is identified. Every animal is going to have a genotype, and thus the purpose of the claim is unclear. Claims which depend from claim 1 are indefinite for this reason as well.

Claim 2 is indefinite over the recitation of “is characterized by a site specific mutation at amino acid...” because it is not clear what “is characterized by” means. This language does not clearly define the polymorphism. Furthermore, as discussed for claim 1 above, it is not clear if this method is intended to be a method for examining a nucleic acid or an polypeptide. Claims which depend from claim 2 are indefinite for this reason as well.

Claim 5 is indefinite over the recitation “wherein marker for lower feed intake, than animals without marker, is identifiable by” because this language is confusing and unclear. It does not appear to be proper English and it is not clear what Applicant is trying to convey. Furthermore the phrase “marker for faster rate of gain” lacks proper antecedent basis in the claim. Furthermore, as discussed for claim 1 above, it is not clear if this method is intended to be a method for examining a nucleic acid or an polypeptide.

Claim 6 is indefinite over the recitation “wherein marker for faster rate of gain, than animals without marker, is identifiable by” because this language is confusing and unclear. It does not appear to be proper English and it is not clear what Applicant is trying to convey. Furthermore the phrase “marker for faster rate of gain” lacks proper antecedent basis in the claim. Furthermore, as discussed for claim 1 above, it is not clear if this method is intended to be a method for examining a nucleic acid or an polypeptide.

Claims 10 and 12 are indefinite over the recitation of “allele specific oligonucleotide primers.” Allele specific primers are generally understood to be designed so that they hybridize exactly to the position of a polymorphism. The primers are designed so that in the presence of one specific allele amplification will occur and in the presence of another amplification will not occur. The primers recited in claim 12, however, are not designed to hybridize to the location of

any particular polymorphism. Thus, if the primers recited in claim 12 are examples of the allele specific primers recited in claim 10, then it is unclear what allele specific oligonucleotide primers actually means.

Claims 20-23, 29-31 and newly added claim 33 are indefinite for failing to recite a final process step which agrees back with the preamble. For example, claims 20-23 are drawn to a method of identifying an animal which possesses a genotype having a genetic marker associated with metabolic traits, yet the claims recite a final step of identifying the presence or absence of a TaqI site in an MC4R gene fragment. The claims do not set forth the relationship between the identifying a TaqI site and the identifying an animal and therefore, it is not clear whether the claims are intended to be drawn to a method for identifying an animal or a method for identifying a TaqI site. Furthermore, claim 20 does not set forth any specific desired genotypes or how these are identified. Independent claims 29 and 33 have similar problems in that they also recite preambles which are not clearly met by the positive process steps of the claims.

Claim 20 is indefinite over the recitation of "possesses a genotype having a genetic marker" because it is not clear how a genotype can have a genetic marker. A genotype is defined as the particular genetic pattern seen in the DNA of an individual. "Genotype" is usually used to refer to the particular pair of alleles that an individual possesses at a certain location in the genome. Thus, the genotype does not have the marker, but describes the allele present at the location of the marker. It would be more appropriate to say that the animal possesses a particular genotype (i.e. a "G" at position 678 of SEQ ID NO: 1) or that the animal possesses nucleic acid comprising a specific version of a marker. Claims which depend from claim 20 are indefinite for this reason as well. In addition claims 31 and 32 recite this same problematic language.

Claim 22 is indefinite over the recitation of “at base 678” because the claim does not clearly set forth what base 678 is referring to.

In line 2 of claim 20, the phrase “restriction pattern” lacks specific antecedent basis in the claim. The claim previously recites separating digested nucleic acid fragments but does not specifically recite a restriction pattern.

Claim 28 is unclear because it recites “a desired polymorphic traits” and thus it is not clear if one or multiple polymorphic traits are being referenced.

Claim 28 is indefinite because it appears to contradict the teachings of the specification. The specification, at page 7, indicates that animals homozygous for allele 1 (that is a G at position 678 of SEQ ID NO: 1) have lower fat content and lower feed consumption, and animals homozygous for allele 2 (an A at position 678 of SEQ ID NO: 1) have a faster rate of weight gain. Yet the instant claim states that to identify animals with lower fat content, faster growth rate, or lower feed content, one must identify a substitution of guanine to adenine (i.e. an “A” at position 678 of SEQ ID NO: 1). This conflicts with the specification’s teaching about the allele that would indicate a faster growth rate. Clarification is required.

Regarding claims 31 and 32, the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Thus, it is not clear if the method is for identifying an animal which possesses a genotype indicative of variation in fat content, growth rate, and feed consumption, or if the method is for detecting an animal which possesses a genotype indicative of variation in any metabolic trait of which those recited are a few examples.

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Claim 31 is indefinite because it appears to recite two different purposes for the method in the preamble of the claim. The claim begins by reciting that the method is for identifying animals which have a desired genotype, but the claim never clearly sets forth a method for identifying such animals. The claim does not provide the desired genotypes to be identified or any guidance as to how to identify which genotypes are “desired.” Next the claim recites a step of determining an association, but the claim does not clearly set forth how the identification of animals is related to the determination of an association.

Claim 33 is indefinite because it is not clear how identifying a polymorphism in step (d) is related to identifying an animal which possesses a **desired** polymorphism as recited in the preamble. Furthermore, the language of step (d) is confusing because it is not clear how to identify a polymorphism “by a nucleotide substitution.” It is not clear if applicant intends to recite that a polymorphism is identified by identifying a nucleotide substitution, or some other process step.

Response to Remarks

Applicants have amended the claims to further define the region of the MC4R gene in which the polymorphism is present, but this amendment is not sufficient to overcome the examiner’s objections with regard to the fact that the claims encompass methods for using polymorphisms and linkage associations as markers for specific metabolic traits when the existence of these additional markers is highly unpredictable and not provided in the specification or the prior art.

Applicant argues the enablement rejection by focusing on a single factor from the test given by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

Applicant focuses on quantity of experimentation and admits that the quantity of experimentation is high, and that it would be complex and time consuming. Applicant correctly notes that this factor in isolation would be insufficient to sustain an enablement rejection. However, the analysis in the rejection focused on all of the factors, including the absence of working examples other than a single polymorphism, the lack of teaching of other polymorphisms in the prior art and the extreme unpredictability of the art. In particular, this unpredictability, combined with the other factors, supports a conclusion of undue experimentation. Unlike the simple screening assay in *Wands* itself, where experimental success was assured so long as sufficient resources were expended, since eventually an antibody producing cell would be isolated, here there is no assurance or even likelihood of success, since there is no reason to believe that other polymorphisms necessarily exist which have the desired correlation. At the time of the invention, it is speculative and without evidentiary basis to predict if there will be any results from the screening for additional polymorphisms, unlike *Wands* where it is not only possible but expected that results will be achieved.

In the response, applicant further discusses the fact that the MC4R gene appears to be highly conserved among species, at least with regard to the portion of the porcine MC4R

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sequence disclosed herein. However, the specification does not show that the mutation itself is present in these other species, merely that it occurs in region of the gene that is highly conserved among species. This showing in no way provides evidence or reason to believe that this particular point mutation would be found in other animal species, nor that it would be an useful marker for specific metabolic traits in other animal species.

The examiner's comments with regard to unpredictability are focused on the fact that it is highly unpredictable as to whether or not any other polymorphisms exist in the porcine MC4R gene OR whether or not the instant polymorphism exists in other species of animals which have a MC4R gene. Although it may be routine experimentation to search for such polymorphisms, this does not subtract from the fact that they actually may not exist. The art is highly unpredictable with regard to the presence and functionality of polymorphic sites in genomic DNA. First, it is unpredictable whether any additional polymorphisms exist in the porcine MC4R gene, or whether the instantly disclosed polymorphism is present in the genomes of other animals. Genetic polymorphisms are the elements which render individuals unique, but many genes are highly conserved and do not yield polymorphisms between individuals of a single species. Some genes even lack polymorphisms between members of different species. The specification and prior art provide no guidance as to whether any other polymorphisms exist, or whether the instantly disclosed polymorphism is present in the genomes of other animals besides pigs. Second, after a screening assay identifies polymorphisms, it is unpredictable whether any such polymorphisms would be associated with favorable meat quality. Thus, the claimed method of screening animals, for enablement of the full scope, requires the use of unpredictable and potentially non-existent products. As noted in *In re Vaeck*, 20 USPQ2d 1438 (CA FC 1991)

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regarding enablement, “This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. Where, as here, a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a "predictable" factor such as a mechanical or electrical element. See Fisher, 427 F.2d at 839, 166 USPQ at 24.” In this case, the genus is itself undefined and undue experimentation is required to identify which polymorphisms, none of which are known other than the disclosed example, have the utility of being associated with metabolic traits in animals.

Applicant further states that claims 1, 28, and 33 are limited to the exact polymorphism (page 10). However, the claims are drawn to be limited to a polymorphism within the “seventh transmembrane domain” or within a restriction site, and are sufficiently broad so as to include other possible polymorphisms. They are not limited to the use of a specific polymorphism. Applicant cites *In re Fisher* as making a point that “as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation *to the entire scope of the claim*, then the enablement requirement of Section 112 is satisfied (emphasis added).” There are two points to be made with regard to this statement. First, the specification provides one of many, many possible polymorphisms whose use is encompassed by the scope of the instant claims, as discussed in the arguments and rejections above. Second, the courts conclusions in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988) supercedes the conclusions in *Fisher*. *Wands* provided a clear set of criteria for the analysis of the enablement question. These criteria have been applied herein, as provided in the rejection and discussed in the arguments.

At page 10, applicant's refute the claim by the examiner that no evidence was provided that the polymorphism observed is causative of the observed traits. However, beyond this assertion, the discussion merely demonstrates that there is an association between the observed traits and the polymorphism. This association is not being disputed. The examiner was merely pointing out that it is not necessarily the case that the polymorphism itself causes the observed traits. This point by the examiner is merely intended to underscore the fact that because it is not clear that the polymorphism is causative of the traits it highly unpredictable as to whether or not markers which are linked to the instantly disclosed polymorphism would be informative for the traits of interest herein.

The rejections under 112 2nd paragraph have been maintained with regard to claims 20-23 and 29-31 for lacking a final process step which agrees with the preamble because the amendment did not adequately address this issue as discussed above. Also, the 112 2nd paragraph rejection over claim 22 for the recitation of "at base 678" was also maintained because the amendment did not clearly address this issue for this claim. New 112 2nd rejections were made to address the amendments to the claims.

For these reasons the rejections are maintained.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


JEFFREY FREDMAN
PRIMARY EXAMINER


Juliet C. Einsmann
Examiner
Art Unit 1655

November 27, 2001